

PACKAGE LEAFLET: INFORMATION FOR THE USER

Omeprazol Mepraz 20 mg gastro-resistant capsules

Omeprazole

Read all of this leaflet carefully before you start taking this medicine as it contains important information for you.

Keep this leaflet. You may need to read it again.

If you are still unsure, ask your doctor, pharmacist or nurse.

This medicine has been prescribed for you only. You should not give it to others. The medicine can be harmful to them even if they show the same signs of illness.

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse.

In this leaflet:

1. What Omeprazol Mepraz is and what it is used for
2. What you need to know before you take Omeprazol Mepraz
3. How to take Omeprazol Mepraz
4. Possible undesirable effects
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1. What Omeprazol Mepraz is and what it is used for

Omeprazol Mepraz contains the active substance omeprazole. It belongs to a group of drugs called 'proton pump inhibitors'. They work by reducing the amount of acid that is produced by the stomach.

Omeprazol Mepraz is used to treat the following:

In adults:

'Gastroesophageal reflux disease' (GERD). This happens when stomach acid escapes into the esophagus (the tube that connects the throat to the stomach) causing pain, inflammation and heartburn.

Ulcers in the upper part of the intestine (duodenal ulcer) or in the stômago (gastric ulcer). Ulcers infected by a bacterium called 'Helicobacter pylori'. If you suffer from this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

Ulcers caused by drugs called NSAIDs (Nonsteroidal Anti-Inflammatory Drugs). Omeprazole Mepraz can also be used to prevent ulcers from forming if you are taking NSAIDs.

Excessive acidity in the stomach caused by an overgrowth of the pancreas (Zollinger-Ellison syndrome).

In children:

Children over 1 year of age and ≥ 10 kg

'Gastroesophageal reflux disease' (GERD). This happens when stomach acid escapes into the esophagus (the tube that connects the throat to the stomach) causing pain, inflammation and heartburn. In children, symptoms of this may include the return of stomach contents to the mouth (regurgitation), malaise (vomiting) and poor weight gain.

Children and adolescents over 4 years of age

Ulcers infected by a bacterium called 'Helicobacter pylori'. If your child suffers from this condition, the doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

2. What you need to know before you take Omeprazol Mepraz

Do not take Omeprazol Mepraz

- if you are allergic (hypersensitive) to the active substance or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- if you are taking a medicine containing nelfinavir (used for HIV infection).

If you are not sure, talk to your doctor or pharmacist before taking Omeprazol Mepraz.

Warnings and precautions

Talk to your doctor or pharmacist before taking Omeprazol Mepraz

- . If you have ever had skin reactions after treatment with a medicine similar to Omeprazole Mepraz that reduces stomach acidity.
- . A specific blood test (ChromograninA) is planned

If you experience a rash, especially on areas of skin exposed to the sun, talk to your doctor as soon as possible, as you may need to stop your treatment with Omeprazole Mepraz. Remember to also mention any other adverse effects, such as joint pain.

Omeprazol Mepraz may mask the symptoms of other diseases. Therefore, if any of the following events happen to you before you start taking Omeprazole Mepraz or while you are taking it, tell your doctor immediately:

You lose a lot of weight for no apparent reason and have difficulty swallowing.

You have stomach pains or indigestion.

Begins to vomit food or blood.

Has black stools (stools stained with blood).

Have severe or persistent diarrhoea as omeprazole has been associated with a small increase in infectious diarrhoea.

You have severe liver problems.

When you take omeprazole, inflammation may occur in your kidneys. Signs and symptoms may include decreased urine volume or blood in the urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report these signs to your treating doctor.

If you take Omeprazole Mepraz in long-term treatment (more than 1 year) your doctor will probably keep you under regular surveillance. You should report any new or unusual symptoms and circumstances every time you see your doctor.

Other medicines and Omeprazol Mepraz

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because Omeprazole Mepraz may affect the mode of action of some medicines and some medicines may affect Omeprazol Mepraz.

Do not take Omeprazol Mepraz if you are taking a medicine containing nelfinavir (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking any of the following medicines:

Ketoconazole, itraconazole, or voriconazole (used to treat infections caused by fungi)

Digoxin (used to treat heart problems)

Diazepam (used to treat anxiety, relax muscles or in epilepsy)

Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor needs to monitor you when you start and when you end treatment with Omeprazol Mepraz

Medicines used to keep your blood flowing, such as warfarin or other vitamin K blockers.

Your doctor may need to monitor you when you start and stop treatment with Omeprazol Mepraz

Rifampicin (used to treat tuberculosis)

Atazanavir (used to treat HIV infections)

Tacrolimus (in cases of organ transplantation)

St. John's wort (*Hypericum perforatum*) (used to treat mild depression)

Cilostazol (used to treat intermittent claudication)

Saquinavir (used to treat HIV infections)

Clopidogrel (used to prevent blood clots (thrombi))

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin along with Omeprazol Mepraz to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Omeprazol Mepraz with food and beverages

You can take gastro-resistant capsules with food or on an empty stomach.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine

Your doctor will decide whether you can take Omeprazol Mepraz during this period.

Your doctor will decide whether you can take Omeprazole Mepraz if you are breast-feeding.

Driving and using machines

Omeprazol Mepraz is unlikely to affect your ability to drive or use tools or machines. Undesirable effects such as dizziness and visual disturbances may occur (see section 4). If you feel affected, you should not drive or use machines.

Omeprazol Mepraz gastro-resistant capsules contain lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Omeprazol Mepraz

Take this medication exactly as directed by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many gastro-resistant capsules you should take and how long you should take them. This will depend on your condition and your age.

The usual doses are given below.

Adults:

To treat GERD symptoms, such as heartburn and acid regurgitation:

If your doctor has detected that your alimentary canal (oesophagus) has been slightly damaged, the usual dose is 20 mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40 mg for another 8 weeks if your oesophagus is not yet healed.

The usual dose after healing of the esophagus is 10 mg once a day.

If your esophagus has not been damaged, the usual dose is 10 mg once a day.

To treat ulcers at the top of the intestine (duodenal ulcer):

The usual dose is 20 mg once daily for 2 weeks. Your doctor may tell you to take the same dose for another 2 weeks if your ulcer is still not healed.

If the ulcer does not heal completely, the dose may be increased to 40 mg once daily for 4 weeks.

To treat non-stomach ulcers (gastric ulcers):

The usual dose is 20 mg once daily for 4 weeks. Your doctor may tell you to take the same dose for another 4 weeks if your ulcer is still not healed.

If the ulcer is not completely healed, the dose may be increased to 40 mg once daily for 8 weeks.

To prevent the return of duodenal and gastric ulcers:

The usual dose is 10 mg or 20 mg once daily. Your doctor may increase the dose to 40 mg once a day.

To treat duodenal and gastric ulcers caused by NSAIDs (Nonsteroidal Anti-Inflammatory Drugs):

The usual dose is 20 mg once daily for 4–8 weeks.

To prevent duodenal and gastric ulcers if you are taking NSAIDs:

The usual dose is 20 mg once a day.

To treat ulcers caused by *Helicobacter pylori* infection and to prevent their return:

The usual dose is Omeprazole Mepraz 20 mg twice daily for one week.

Your doctor will also tell you to take two antibiotics between amoxicillin, clarithromycin and metronidazole.

To treat excessive acidity in the stomach caused by a growth of the pancreas (Zollinger-Ellison syndrome):

The usual dose is 60 mg per day.

Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine.

Use in children:

To treat GERD symptoms, such as heartburn and acid regurgitation:

Children over 1 year of age and with a body weight of more than 10 kg can take Omeprazole Mepraz. The dose for children is based on the child's weight and the doctor will decide what the correct dose is.

To treat ulcers caused by *Helicobacter pylori* infection and to prevent their return:

Children over 4 years of age can take Omeprazole Mepraz. The dose for children is based on the child's weight and the doctor will decide what the correct dose is.

The doctor may also prescribe the child two antibiotics called amoxicillin and clarithromycin.

Taking this medicine

It is recommended to take gastro-resistant capsules in the morning.

You can take gastro-resistant capsules with food or on an empty stomach.

Gastro-resistant capsules should be swallowed whole with half a glass of water. Do not chew or crush the gastro-resistant capsules. This is because gastro-resistant capsules contain coated granules (medicated pellet) that prevent the medicine from being destroyed by stomach acid. It is important not to damage the granules (medicated pellet).

If there is difficulty swallowing the gastro-resistant capsules

If you or your child have difficulty swallowing gastro-resistant capsules:

Open the gastro-resistant capsule and ingest the contents directly with half a glass of water or mix the contents in a glass with non-carbonated water, or any acidic fruit juice (e.g. apple, orange or pineapple) or applesauce.

Always shake the mixture just before drinking it (the mixture will not be clear). Then drink the mixture immediately, or within 30 minutes.

To make sure you have drunk all the medicine, rinse the glass thoroughly with half a glass of water and drink the contents. Solid granules contain the medicine – do not chew or crush them.

If you take more Omeprazol Mepraz than you should

If you take more Omeprazole Mepraz than your doctor prescribes, contact your doctor or pharmacist immediately.

If you forget to take Omeprazol Mepraz

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for the missed dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible undesirable effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following rare but serious side effects, stop taking Omeprazole Mepraz and contact a doctor immediately:

Sudden difficulty breathing, swelling of your lips, tongue and throat or body, rash, loss of consciousness or difficulty swallowing (severe allergic reaction).

Redness of the skin with blistering or peeling of the skin. Severe blistering and bleeding from the lips, eyes, mouth, nose, and genitals may also occur. This may be "Stevens-Johnson syndrome" or "toxic epidermal necrolysis".

Yellow skin, dark-colored urine, and tiredness, which can be symptoms of liver problems.

Undesirable effects may occur with some frequency, as defined below:

Very common:	Affect more than 1 in 10 users
Frequent:	They affect between 1 and 10 users in 100
Uncommon:	They affect between 1 and 10 users in every 1,000
Rare:	They affect between 1 and 10 users in every 10,000
Very rare:	Affect less than 1 user in 10,000
Unknown:	Frequency cannot be calculated from the available data

Other undesirable effects include:

Common undesirable effects

Headache.

Benign polyps in the stomach

Effects on your stomach or intestines: diarrhoea, stomach pain, constipation, passing gas more often (flatulence).

General malaise (nausea and vomiting).

Uncommon undesirable effects

Swelling of the feet and ankles.

Difficulty falling asleep (insomnia).

Dizziness, tingling sensation like "needle", drowsiness.

Spinning sensation (dizziness).

Change in blood tests that show how the liver works.

Rash, hives and itchy skin.

Feeling of general malaise and lack of energy.

Rare undesirable effects

Changes in the blood, such as a reduction in the number of white blood cells or platelets.

This can cause weakness, bruising or infections more easily.

Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, difficulty breathing.

Low levels of sodium in the blood. This can cause weakness, malaise (vomiting) and cramps.

Feeling agitated, confused, or depressed.

Alteration of taste.

Vision problems such as blurred vision.

Sudden feeling of difficulty breathing or shortness of breath (bronchospasm).

Dry mouth.

Inflammation inside the mouth.

An infection called a "cold sore" that can affect the intestine and is caused by a fungus.

Liver problems, including jaundice, which can lead to yellow skin, dark-colored urine, and tiredness.

Hair loss (alopecia).

Rash of the skin when exposed to the sun.

Joint pain (arthralgia) and muscle pain (myalgia).

Severe kidney problems (interstitial nephritis).

Increased sweating.

Very rare undesirable effects

Changes in blood cell count, including agranulocytosis (lack of white blood cells).

Aggressiveness.

Seeing, feeling, and hearing things that don't exist (hallucinations).

Severe liver problems that lead to liver failure and inflammation in the brain.

Sudden onset of severe rash, blistering, or peeling of the skin. This may be associated with high fevers and joint pain (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).

Muscular weakness.

Breast development in men.

Hypomagnesemia.

Frequency not known: rashes, possibly accompanied by joint pain

Omeprazol Mepraz may, in very rare cases, affect white blood cells leading to an immune deficiency. If you have an infection with symptoms such as fever with a severe general minor condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulty urinating, you should contact your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be detected through blood tests. It is important for you to provide information about your medication at this time.

Do not be alarmed by this list of possible undesirable effects. You may not feel any of them. If any of the undesirable effects get serious or if you notice any undesirable effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of undesirable effects

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report undesirable effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you are helping to provide more information about the safety of this medicine.

Sítio da internet: <http://www.infarmed.pt/web/infarmed/submissaoram>
(preferably)

or through the following contacts:

Direção de Gestão do Risco de Medicamentos

Parque da Saúde de Lisboa, Av. Brasil 53

1749-004 Lisboa

Tel: +351 21 798 73 73

Linha do Medicamento: 800222444 (gratuita)

5. How to store Omeprazol Mepraz

Do not store above 30 °C. Store in a dry place.

Keep this medicine out of the sight and reach of children.

Do not use Omeprazol Mepraz after the expiry date which is stated on the carton after 'EXP'. The expiry date corresponds to the last day of the month indicated.

Do not dispose of any medicines in the sewer or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Package contents and other information

What Omeprazole Mepraz contains

The active substance is omeprazole. Omeprazole Mepraz gastro-resistant capsules contain 20 mg of omeprazole.

The other components are:

Neutral pellets, L-Hydroxypropyl cellulose, Hydroxypropyl methylcellulose, Diethyl phthalate, Hydroxypropyl methylcellulose phthalate, Disodium phosphate anhydrous, Sodium lauryl sulfate, Lactose monohydrate. Qualitative composition of neutral pellets: Sucrose and Corn Starch. Qualitative composition of capsule shells: Titanium Dioxide, Indigocarmine and Gelatin.

What Omeprazole Mepraz looks like and contents of the pack

Gastro-resistant capsules are packaged in a bottle. The presentations are of 10, 30 and 60 capsules.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturers

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